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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/502,945	SCANLAN ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,37-40 and 57-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,37-40 and 57-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 September 2003 has been entered. Claim 6 is amended.

Claims 6, 37-40, and 57-67 are pending, and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejection.

Claim Rejections - 35 USC § 112, Maintained

Claim 6 remains rejected for reason of record, and the dependent claims 57-61 is newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant argues that the limitation that the nucleic acid molecules encode a cancer antigen, but the encoded antigen "stimulates an immune response". The inclusion of the language 'stimulates immune response" provide sufficient description of protein

structure and activity. Applicant argues that the Office may have overlooked the addition of this limitation to claim 6 in maintaining the rejection, has only addressed the inclusion of the phrase "encode a cancer antigen." These arguments have been fully considered but found unpersuasive for following reasons for the following reasons:

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; and Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Instant claim 6 reads:

> An isolated protein encoded by an isolated nucleic acid molecules selected from the group consisting of:
>
> (a) nucleic acid molecules which encode a cancer antigen that stimulates an immune response, and which comprises a nucleotide sequence, the complementary sequence of which hybridizes, under stringent conditions, to at least one second nucleic acid molecules comprising a nucleotide sequence selected from the group consisting of the nucleotide sequences set forth as SEQ ID NOs: 1, 2, 3, 4, and 5,
>
> (b) nucleic acid molecules that differ from the nucleic acid molecules of (a) in codon sequence due to the degeneracy of the genetic code, and
>
> (c) full length complements of (a) or (b), wherein the stringent conditions are hybridization at 65°C, in hybridization buffer (3.5x SSC, 1x Denhardt's solution; 25 M sodium phosphate buffer (pH 7.0), followed by four washes (one hour, each wash, at 65°C., 2xSSC, 0.1% SDS), and a final wash for 30 minutes at 1.0xSSC 0.2% SDS.

The claim as currently construed encompasses a genus of proteins with unrelated structures as long as they are cancer antigens that stimulate immune response. The specification teaches instant SEQ ID NO:1-5, all human cDNAs with unrelated structures have been isolated through SEREX method, an immunoscreening technique using a cancer patient's serum containing autoantibodies. The disclosure indicates that the SEQ ID NOs:1-5 encode antigens recognized by an immune system of an autologous host. The specification at pages 9-13 teaches that SEQ ID NOs:1-4 isolated through the SEREX technique are novel gene products, and SEQ ID NO:5 is a splicing variant of SEQ ID NO:4. SEQ ID NOs: 1-4 do not share any structural similarities. Proteins encoded by SEQ ID NO:1-4 do not share common structures, they encode totally different proteins with different structures. Functions of these proteins are not known yet. The specification does not teach what is the biological or chemical function(s) of the encoded proteins.

First, claim 6 (c) says that a protein is encoded by a complement of a nucleic acid sequence but the specification does not describe any protein encoded by complement of a coding sequence. All of the cancer proteins disclosed in the instant application are human origin, therefore it is highly unlikely that an antisense (a complement of a coding sequence) encodes any protein. Peltz et al at page 1729 (1999, J. Exp. Med. Vol. 190, pages 1729-1731) teach that antisense of mammalian genes do not usually code for anything except in a rare occasion.

A description of a genus of proteins may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequences, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. However, SEQ ID NOs:1-4 do not share common structures. The specification does not teach any other species that share common structure to SEQ ID NO:1-4.

Scalan et al (1998, Int. J. Cancer, vol. 76, pages 652-8, cited in the Office action mailed on 3/13/2003) teach that SEREX is an art-accepted way of screening which antigen is a tumor antigen. Therefore, the Office accepts that protein encoded by instant SEQ ID NO:1-5 are tumor antigens expressed in colon cancer. Scalan et al., at Table IA and 1B teach that numerous proteins structurally not related to the proteins encoded by instant SEQ ID NOs:1-5 are cancer antigens that are isolated by SEREX method, which indicates that these unrelated proteins also stimulate immune response in the autologous host. In other words, only way one would know whether a protein is a cancer antigen that stimulates a immune response is to screen for it using SEREX or other art-known methods summarized at page 652, left column of Scalan et al., (cited above). Numerous other proteins without any structural similarities to instant proteins encoded by instant SEQ ID NOs:1-5 are expressed in colon cancers and their cDNAs could be screened by SEREX.

The only factor present in the claim 6 (c) is hybridization conditions and the nucleotide molecules that need to be hybridized to. Since no structure is

specified in step (c), and one does not know what kind of protein(s) is encoded by the hybridizing nucleotide molecules, the limitation in step (b) compounds the written description problem started in step (a). How does one know what degenerate codon(s) when no protein structure is defined in first place? There is not even identification of any particular portion of the structure that must be conserved in order to have the recited function. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. description requirement of a representative number of species OR by disclosure or relevant identifying characteristics, such as structure or other physical and/or chemical properties, OR by functional characteristics coupled with a known or disclosed correlation between function and structure

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed protein genus, given that the specification has only described SEQ ID NO: 1-5. Therefore, proteins encoded by isolated nucleic acid comprising SEQ ID NO:1-5, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

The functional characteristic recited is uncoupled with the structure of the claimed genus. There is no correlation between the chemical structure of the claimed genus and the recited function. Therefore the recited functional language describing the claimed genera does not adequately describe the common feature of claimed generic proteins. Since SEQ ID NO:1-4 are different cDNAs as stated in the previous Office action, the breath of the claims is broad as reading on genes yet to be discovered, the lack of correlation between the structure(s) and the function of the genus, it is concluded the specification fails to describe genus. The dependent claims 57-61 are also rejected because they depend on the rejected base claim 6.

Claims 6, and 57-61 remain rejected for reason of record under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection due to the hybridizing condition in claim 6 (c).

> hybridization at 65°C, in hybridization buffer (3.5x SSC, 1x Denhardt's solution; 25 M sodium phosphate buffer (pH 7.0), followed by four washes (one hour, each wash, at 65°C., 2xSSC, 0.1% SDS), and a final wash for 30 minutes at 1.0xSSC 0.2% SDS

Applicant argues that the hybridization condition was incorporated by US Pat. 5,698,396 in the specification at page 4 lines 12-14. A close review of the

specification reveals that there is no statement that the patent was incorporated in its entirety. The specification at the bottom half of page 4 reasonably communicates the SEREX technology from the three incorporating documents were incorporated, not nucleotide hybridizing conditions recited in the instant claim 6. Further, the instant specification at page 13 lines 17-21 certain hybridization conditions were incorporated by US Pat. 5,342,774, which are different from the instantly recited conditions.

The Following are New Grounds of Rejections

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 08/948,705, filed 10/10/1997. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen

months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Objections

Claim 6 is objected to because of the following informalities: claim 6 recites "(3.5x SSC, 1x Denhardt's solution; 25 M sodium phosphate buffer (pH 7.0), followed by four washes (one hour, each wash, at 65°C., 2xSSC, 0.1% SDS)". Inconsistent punctuations are used for the quoted limitation. Amending the limitation to "(3.5x SSC, 1x Denhardt's solution, 25 M sodium phosphate buffer at pH 7.0), followed by four washes (one hour, each wash, at 65°C, 2xSSC, 0.1% SDS)" would obviate this rejection. Appropriate correction is required.

Allowable Subject Matter

The indicated allowability of claims 37-40, and 62-67 are withdrawn in view of the new rejection below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 57-61 recite "the nucleic acid molecule" in line 1 of the claims. But it is not clear which "nucleic acid molecule" of the base claim the recited limitation of claim 57-61 is referring to. The base claim 6 has "nucleic acid molecule" in

line 1 and line 5. It is not clear the nucleic acid molecule" in line 1 of claims 57-61 refer to "nucleic acid molecule" in line 1 or "nucleic acid molecule" in line 5 of claim 6. The scope of the claims 57-61 depend on what the limitation is referring to in the base claim.

Claims 6, and 57-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for proteins encoded by SEQ ID NOs:1-5, does not reasonably provide enablement for the proteins encoded by hybridizing nucleic acid molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Claims 6, and 57-61 are interpreted as drawn to various proteins encoded by SEQ ID NO:1-5, and also encoded by nucleic acid molecules hybridizing to SEQ ID NO:1-5 under the recited conditions.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The specification teaches instant SEQ ID NO:1-5 (all human cDNAs) have been isolated through SEREX method, an immunoscreening technique using a cancer patient's serum containing autoantibodies. The disclosure indicates that the SEQ ID NOs:1-5 encode antigens recognized by an immune system of an autologous host. The specification at pages 9-13 teaches that SEQ ID NOs:1-4 isolated through the SEREX technique are novel gene products, and SEQ ID NO:5 is a splicing variant of SEQ ID NO:5. SEQ ID NOs: 1-4 do not share any structural similarities. Proteins encoded by SEQ ID NO:1-4 do not share common structures, they encode totally different proteins with different structures.

The nature of the claimed invention is multiple proteins without any structure recited in the claims. The claimed invention includes at least 5 proteins unrelated in terms of structures and/or their biological functions. What is common to all of the claimed proteins, is they are cancer antigens that stimulate immune response.

The relative level of skill in the art in determining which nucleic acid molecules hybridizes to a given nucleic acid is high. However, the relative level of skill in the art in determining which protein is a cancer antigen that stimulates an immune response is limited. Scalan et al (1998, Int. J. Cancer, vol. 76, pages 652-8, cited in the Office action mailed on 3/13/2003) teach that only way one would know whether or not a given protein is a cancer antigen that stimulates an immune response is to determine experimentally involving clinical samples. Scalan et al., (cited above) summarize the methods used in the art including

SEREX at page 652, left column. Thus, in order to make proteins that are cancer antigens that stimulate an immune response, one skilled in art has to screen for them. In other words, the relative high level in determining which nucleic acid molecules hybridizes to a given nucleic acid is not applicable to predict which other similar sequence(s) to the proteins encoded by instant SEQ ID NO:1-5 are cancer antigens that stimulate an immune response. Which other similar protein sequence is a cancer antigen that stimulates an immune response, is still unpredictable and requires undue experiment because this process involves screening a large quantity of appropriate clinical samples. Note Material and Methods of Scalan et al (cited above) at page 652-3.

The breadth of the claims is broad including unknown species. The level of predictability which protein is a cancer antigen that stimulates an immune response is low; Scalan et al also teach at Table 1A and 1B that numerous other proteins without any structural similarities to proteins encoded by instant SEQ ID NOs:1-5 are expressed in colon cancers. The amount of direction or guidance by the inventor how to make the full scope of claimed proteins with the recited structural elements coupled with the recited function is limited. There are no working examples or guidance or direction to allow the person of ordinary skill in the art to make species in a manner commensurate in scope with the claims. The quantity of experimentation needed to make the invention is large. In order to make the full scope of the invention, one skilled in the art has to screen a large quantity of clinical samples from all kinds of cancer samples.

Considering the unpredictable state of art, limited guidance, no examples of proteins encoded by the hybridizing nucleic acid molecules acting as a cancer antigen, how to make the full scope of the instantly claimed invention, broad breath of the claims, it is concluded that undue experimentation is required to practice the invention. It is noted that law requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves.

Claims 37-40, and 62-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 37, 38-40, and 62-67 are drawn to a composition comprising a plurality of immunogenic peptides derived from the amino acid sequence of at

least one protein of proteins encoded by SEQ ID NO:1-5. Applicant at page 4-5 of the amendment filed on 06/06/2003 traversing the art rejection of record, stated that the claimed invention is composition comprising plurality of peptide fragments of the amino acid sequences encoded by SEQ ID NOs:1-5, wherein peptide fragments bind to one or more MHC molecules presented on the surface of cells.

The specification at page 14 states that "T cell responses may be elicited by using peptides derived from the proteins which then complex, non-covalently, with MHC molecules, thereby stimulating proliferation of cytolytic T cells against any such complexes in the subject." However, the specification does teach which fragment or derived peptides claimed in the instant claims can be used to stimulate immune response and binds to one or more MHC molecules presented on the surface of cells, elicit a cytolytic response. It is not clear if (CTLs) could be generated using any fragment of SEQ ID:1-5.

One cannot extrapolate the teaching of the specification to the claimed invention of claims 37, 38-40, and 62-67, because there is no guidance on or exemplification of any correlation between any peptide derived from proteins encoded by nucleotides comprising SEQ ID NO:1-5, wherein capable of specifically activating cytotoxic T lymphocytes (CTLs) with claimed specifity/activity. The specification does not disclose common structural attributes that stimulate an immune response and binds to one or more MHC molecules presented on the surface of cells. There is insufficient guidance regarding the parameters and sequence of peptides which correlate with the

ability to stimulate T cell with any MHC molecule and generate CTLs with claimed specifity/activity. There is insufficient guidance regarding selection of peptides that meet the instant criteria of stimulating T lymphocytes with specific activity. Thus, there is insufficient guidance regarding the parameters and sequences of peptides which correlate with the ability to be recognized by the specific CTL clone.

Riott et al (Immunology, Fourth Edition, 1996, Mosby, page 7.9-7.11) teach that T cells recognizes cell-bound antigen in association with MHC molecules. MHC class I and class II act as guidance systems for T cells. This is known as MHC restriction. Only a minority of peptide fragments from a protein antigen is able to bind particular MHC molecules. Different MHC molecules bind different sets of peptides. Riott et al specifically teach Fig. 7.22 and Fig. 7.23, and also page 7.10, right column that the peptides sizes 12-15 are optimal for MHC molecule class I and certain amino acids at certain positions are critical for binding to MHC class I.

US Pat. 5,840,839 (Nov. 24, 1998, cited in the Office action mailed on 3/13/2003) teach at column 19 that finding a peptide that binds to a MHC molecules and stimulates immune response is not a trivial matter. The '839 patent at column 19, lines 53 to 67 teaches that structure a T cell epitope that stimulates immune response in context of MHC molecules is unpredictable in the current state of art. The '839 patent at columns 19-20, and Table 1 teaches that the various candidate T cell epitopes selected based on theoretical binding motif of one class of MHC molecule, i.e. HLA-A31 do not work when they are

experimentally tested as shown in Table 1. This suggests that theoretically selected T cell binding motifs have to be tested experimentally in order to determine whether they are actually T cell epitopes or not.

The specification provides insufficient guidance with regard to theses issues and provides no working examples of a peptide that would work with any MHC molecule. Considering the state of art, the broad scope of claims in respect to the nature of peptide and also to the nature of MHC molecules, it is concluded that that undue experimentation is required to practice the claimed invention. It is noted that law requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina C Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

LARRY R. HELMS, PH.D
PRIMARY EXAMINER